REMARKS

Claims 1 – 17 have been cancelled and new claims 18 – 34 have been added. Amendments have been made to eliminate multiple dependencies and to bring the application into more traditional US format. No new material has been added. In view of the above amendment, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 08-0750, under Order No. 4171-000002/US/NP from which the undersigned is authorized to draw.

Dated: June 11, 2007

Respectfully submitted,

By _____

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PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	See form PCT/ISA/210
Applicant's or agent's file reference FP.CHRU002/WO	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/FR2005/002056	09.08.2005	20.09.2004

International Patent Classification (IPC) or both national classification and IPC
A61B5/0452

Applicant
CENTRE HOSPITALIER REGIONAL UNIVERSITAIRE DE LILLE

1. This opinion contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/EP	Authorized officer
Facsimile No.	Telephone No.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
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Box No. III **Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 1-9,13-17

because:

☒ the said international application, or the said claims Nos. 1-9,13-17 relate to the following subject matter which does not require an international preliminary examination (*specify*):

See supplemental box

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 1-9,13-17

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☒ See Supplemental Box for further details.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/FR2005/002056

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	11-12	YES
	Claims	10	NO
Inventive step (IS)	Claims		YES
	Claims	10-12	NO
Industrial applicability (IA)	Claims	10-12	YES
	Claims		NO

2. Citations and explanations:

1. Reference is made to the following documents:

D1: WO 03/057034 A (MEDIWAVE STAR TECHNOLOGY, INC; STAROBIN, JOSEPH M; CHERNYAK, YURI B) 17 July 2003 (2003-07-17)

D2: US-A-5 341 811 (CANO ET AL) 30 August 1994 (1994-08-30)

D3: WO 03/084396 A1 (ASPECT MEDICAL SYSTEMS, INC) 16 October 2003 (2003-10-16)

2. CLARITY

Claims 10-12 are unclear (PCT Article 6) because they refer to claims 1-9, which have not been searched. It is possible to eliminate this objection by changing the wording of the claims in the following way: "Claim 10: system...[features of claim 10]...the treatment means of which are designed to: [instructions from claims 1-9]."

3. NOVELTY AND INVENTIVE STEP

Moreover, notwithstanding the aforementioned lack of clarity, the subject matter of claim 10 is not novel in the sense of PCT Article 33(2); consequently, the requirements set forth in PCT

Article 33(1) have not been met.

The present application does not meet the requirements set forth in PCT Article 33(1) in that the subject matter of claims 11-12 does not involve an inventive step as defined by PCT Article 33(3).

2.1 CLAIM 10

Document D1 describes the subject matter of claim 1 (the references in parentheses apply to this document):

System for analysing cardiac rhythm variability (page 1, lines 12-13), said system comprising means for acquiring an analog cardiac signal (figure 3 (30)), means for sampling this cardiac signal (figure 3 (31)), and means for processing the sampled signal (figure 3 (32)) designed to generate an RR series composed of a plurality of samples representing the time intervals between two successive heartbeats or the inverse of these time intervals, characterized in that said processing means are also designed to automatically calculate at least one final parameter from the series according to the following method:

Method for processing an RR series composed of a plurality of samples representing the time intervals between two successive heartbeats or the inverse of these time intervals, characterized in that samples are selected in a main time window of predefined duration, this time window is divided

into sub-windows, for each sub-window an intermediate parameter is calculated from the samples contained in the sub-window, and a final parameter that is a function of the intermediate parameters is calculated (p. 33, lines 5-17).

Document D2 also describes the subject matter of claim 1.

2.2 CLAIMS 11-12

Dependent claims 11-12 do not contain any features, which in combination with those of any of the claims to which they refer, define a subject matter that meets the requirements of the PCT in respect of inventive step, the reasons being as follows:

Claims 11-12: D3, page 3.

3 AMENDMENTS

If the applicant files new claims, he should take the following points into account:

3.1 The applicant is requested to indicate in the response letter the difference between the new claim and the prior art (D1 and D2)(PCT Article 33(2)) and to indicate how the claim involves an inventive step (PCT Article 33(3)). In his argument, the applicant is requested to use the problem-solution approach from the Guidelines (Appendix of Chapter 13).

3.2 The applicant must also take into account PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/FR2005/002056

Box No. V **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Article 19(2) and 34(2)(b).

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

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Box No. VII **Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

1. The independent claims are not formulated correctly in the two-part form in accordance with PCT Rule 6.3(b), with those features known in combination from the prior art being placed in the preamble (PCT Rule 6.3(b)(i)), and the remaining features being placed in the characterising part (PCT Rule 6.3(b)(ii)).

2. Contrary to the requirements of PCT Rule 5.1(a)(ii), the relevant prior art disclosed in document D1 is not mentioned in the description, nor is this document identified therein.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: Box III

The subject matter of claims 1-9 and 13-17 refers to diagnostic methods practiced on a living being for the purpose of obtaining results that alone enable a decision to be made as to the treatment required (for example arrhythmia treatment).

The subject matter of claims 1-9 refers to diagnostic methods practiced on a living being in order to obtain results that alone enable a decision to be made as to the treatment required (pain treatment).

According to the PCT, no authority is obliged to perform a search (PCT Rule 39.1(iv)) or an international preliminary examination (PCT Rule 67.1(iv)) on a subject matter of this nature.